510(k) Summary

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780

NOV - 2 2006

CONTACT PERSON:	Mary E. Gray
DATE PREPARED:	July 28, 2006
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation, Spinal Intervertebral Body Fixation
PROPRIETARY NAME:	EXPEDIUM Spine System
PREDICATE DEVICES:	EXPEDIUM Spine System (K051024), EXPEDIUM 5.5mm Commercially Pure Titanium (K052131), EXPEDIUM™ Spine System (K041119) and EXPEDIUM™ Spine System cleared as Merlin Spine System (K033901), MONARCH® Spine System (K021148, K010576), and MOUTAINEER™ OCT Spine System (K041203) and ISOLA® Spine System (K944756).
DEVICE DESCRIPTION:	EXPEDIUM Spine System components are designed to accept a 6.35mm rod and are available in various geometries and sizes. The EXPEDIUM Spine System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification
INTENDED USE:	The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

MATERIALS:	Manufactured from ASTM F-138 implant grade stainless steel and ASTM F-136 or ASTM F-67 implant grade titanium alloy.
PERFORMANCE DATA:	Performance data were submitted to characterize the EXPEDIUM Spine System components subject of this notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Depuy Spine Incorporated
c/o Mr. Christopher Klaczyk
325 Paramount Drive
Raynham, Massachusetts 02780

NOV - 2 2006

Re: K062174
Trade Name: EXPEDIUM Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNH,MNI, KWQ, KWP
Dated: October 3, 2006
Received: October 4, 2006

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062174

Device Name: EXPEDIUM™ Spine System

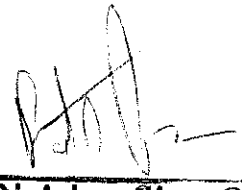
Indications For Use:

The EXPEDIUM™ Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorat
and Neurological Devices

510(k) Number K062174